Generic medicines policies in Italy

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Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	X	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	X	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	X	☐	☐	☐ optional
2. Consultancy for a company	X	☐	☐	☐ optional
3. Strategic advisory role for a company	X	☐	☐	☐ optional
4. Financial interests	X	☐	☐	☐ optional
5. Ownership of a patent	X	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	X	☐	☐	☐ optional
7. Investigator	X	☐	☐	☐ optional
8. Grant or other funding	X	☐	☐	☐ optional
9. Family members interests	X	☐	☐	☐ optional

*Giovanni Tafuri, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. I am not receiving any compensation

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Generic policies: key features and updates

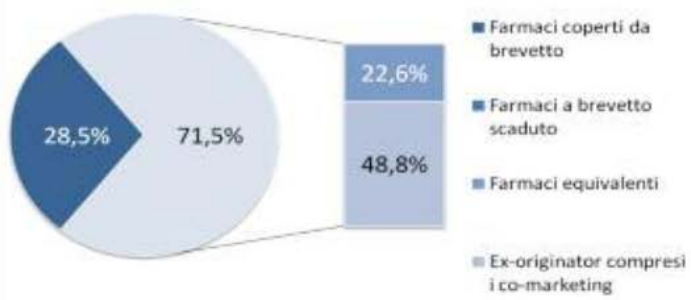
•Physicians can prescribe INN

•Pharmacists can suggest to replace branded with generic medicine, unless otherwise specified by the physician. Co-payment for branded products.

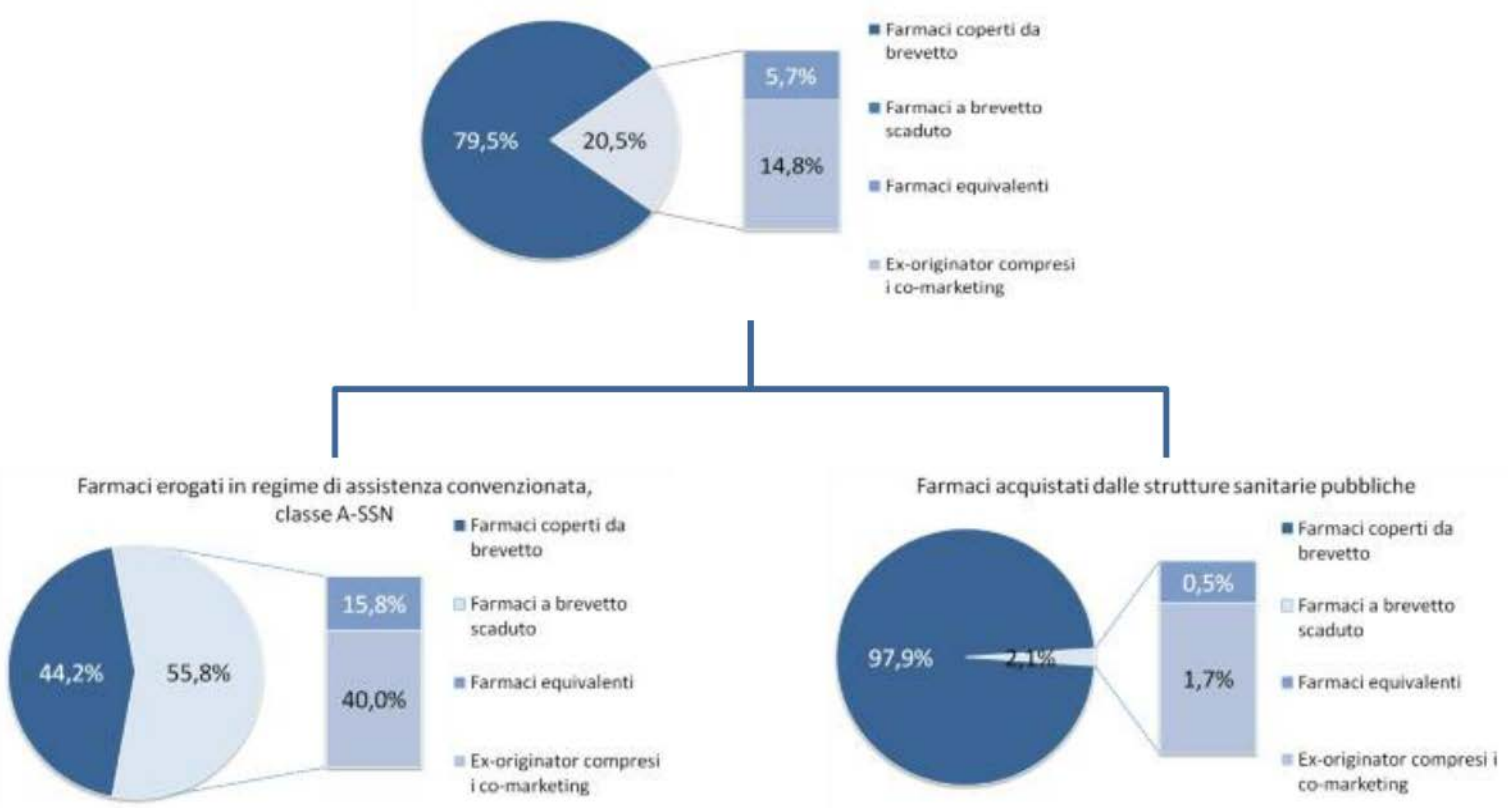
•Regular publication of price lists of generic medicines (*lists of transparency*), a technical tool for all stakeholders provided by AIFA to foster NHS sustainability

• Latest update: Financial Law 2017: for procurement purposes, biosimilars can compete with their own originators.

Consumptions for in-patent and off-patent medicines: Jan-Sept 2016 (OsMed report)



NHS expenditure for in-patent and off-patent medicines: Jan-Sept 2016 (OsMed report)



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Impact of generics on drug expenditure and consumptions per ATC in Italy (year 2015), OsMed 2015

ATC I livello	Spesa (Ass. convenzionata e strutture sanitarie pubbliche)		Consumo -DDD (Ass. convenzionata e strutture sanitarie pubbliche)	
	% Brevetto scaduto per categoria terapeutica	% Generico per area terapeutica	% Brevetto scaduto per categoria terapeutica	% Generico per area terapeutica
A	46,2%	16,3%	70,6%	23,9%
B	7,3%	2,0%	61,0%	10,4%
C	56,0%	14,4%	83,2%	28,5%
D	23,5%	4,9%	8,8%	1,5%
G	30,3%	8,9%	61,1%	20,4%
H	15,3%	0,8%	69,5%	2,6%
J	20,4%	5,1%	77,0%	20,9%
L	3,9%	0,9%	43,1%	21,8%
M	41,3%	9,5%	67,1%	21,9%
N	15,8%	5,1%	59,2%	27,1%
P	5,5%	1,1%	7,4%	3,6%
R	11,8%	1,9%	34,0%	7,1%
S	12,9%	2,1%	38,7%	10,4%
V	1,9%	0,3%	7,9%	1,2%

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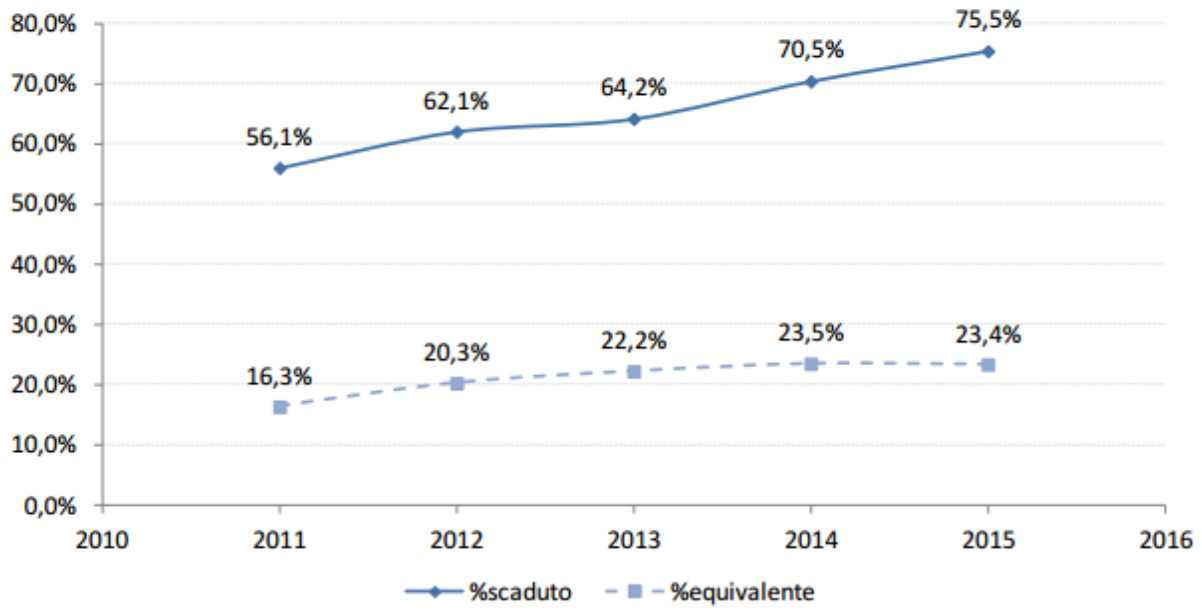
Consumptions of off-patent and generic medicines over total consumption of NHS reimbursable retail products

Figura 7.3.4. Andamento dell'incidenza del consumo (dosi) dei farmaci a brevetto scaduto e dei farmaci equivalenti sul totale del consumo dei farmaci classe A-SSN nel periodo 2011-2015



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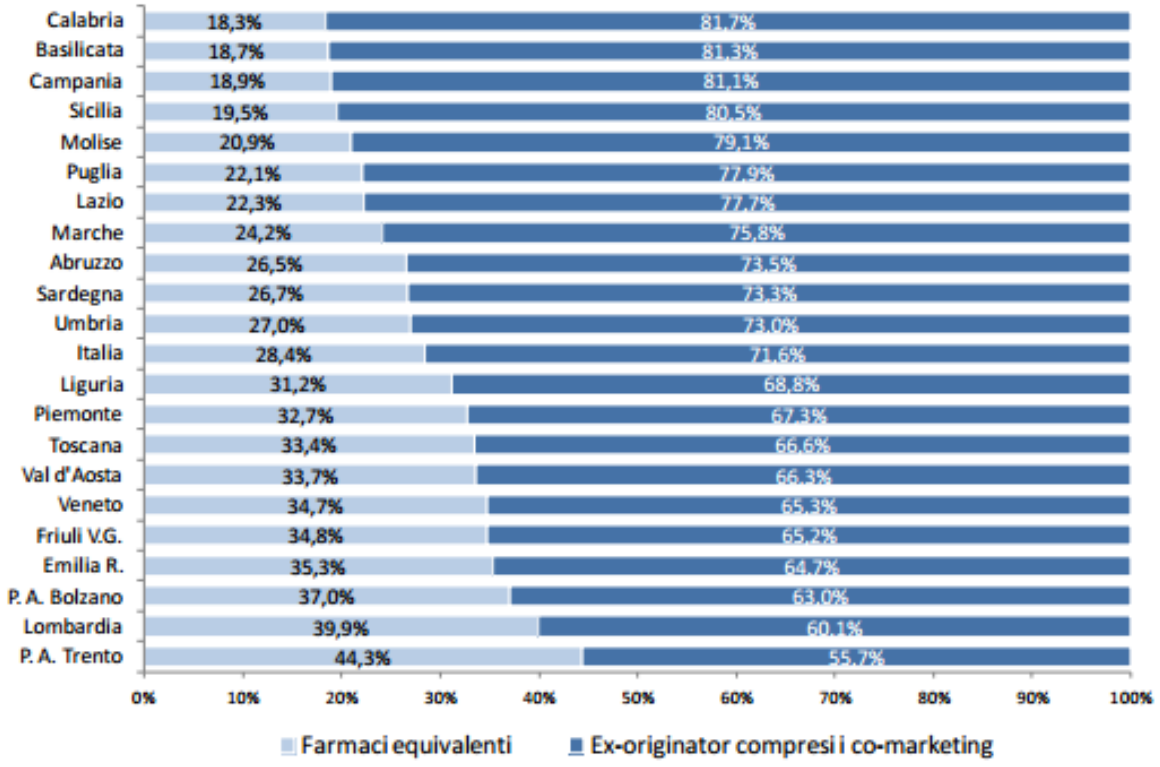
Regional expenditure of off-patent and generic retail medicines reimbursed by the NHS

Figura 7.3.5. Composizione per Regione della spesa netta 2015 per i farmaci a brevetto scaduto di classe A-SSN



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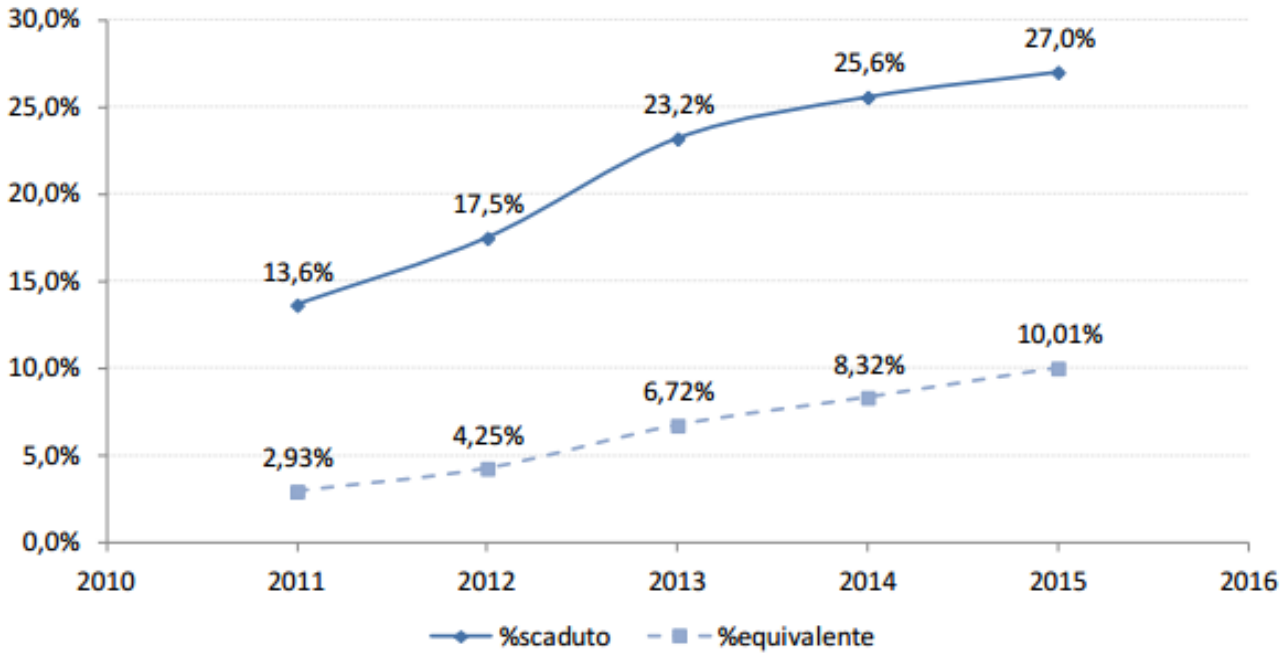
Consumptions of off-patent and generic medicines over total consumption of products purchased by NHS bodies

Figura 7.3.7. Andamento dell'incidenza della consumo (dosi) dei farmaci a brevetto scaduto e dei farmaci equivalenti sul totale del consumo dei farmaci acquistati dalle strutture sanitarie pubbliche nel periodo 2011-2015



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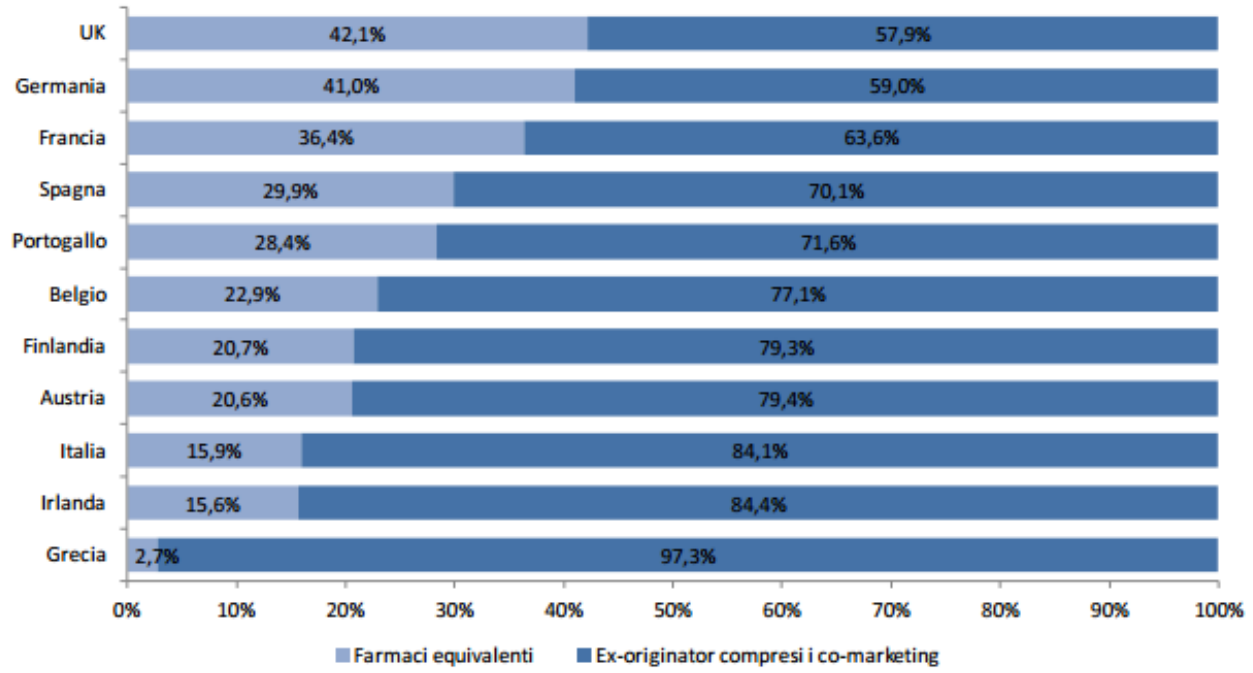
International comparison of retail expenditure (generics and off patent medicines) across countries

Confronto internazionale

Figura 7.3.9. Confronto internazionale della distribuzione percentuale della spesa farmaceutica territoriale* 2015 per i farmaci a brevetto scaduto



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The AIFA position paper on biosimilars

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15 giugno 2016

SECONDO CONCEPT PAPER AIFA SUI FARMACI BIOSIMILARI

Preparazione del Draft	06.07.2012
Approvazione del Draft e rilascio per la consultazione pubblica	25.07.2012
Inizio della consultazione pubblica	1.08.2012
Fine della consultazione pubblica	31.10.2012
Versione definitiva	13.05.2013
Inizio della seconda consultazione pubblica	6.03.2014
Fine della seconda consultazione pubblica	15.05.2014
Inizio della terza consultazione pubblica	15.06.2016
Fine della terza consultazione pubblica	15.09.2016
Nuova versione definitiva	--.--.----

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The importance of Real World Data for biosimilars

Open Access Research

BMJ Open

Comparative effectiveness and safety of erythropoiesis-stimulating agents (biosimilars vs originators) in clinical practice: a population-based cohort study in Italy

Francesco Trotta,[1] Valeria Belleudi,[1] Danilo Fusco,[1] Laura Amato,[1] Alessandra Mecozzi,[2] Flavia Mayer,[1] Massimo Sansone,[2] Marina Davoli,[1] Antonio Addis[1]

BioDrugs (2017) 31:117–124
DOI 10.1007/s40259-017-0214-9

ORIGINAL RESEARCH ARTICLE

Impact of Guidance on the Prescription Patterns of G-CSFs for the Prevention of Febrile Neutropenia Following Anticancer Chemotherapy: A Population-Based Utilization Study in the Lazio Region

Francesco Trotta[1] · Flavia Mayer[1] · Alessandra Mecozzi[2] · Laura Amato[1] · Antonio Addis[1]

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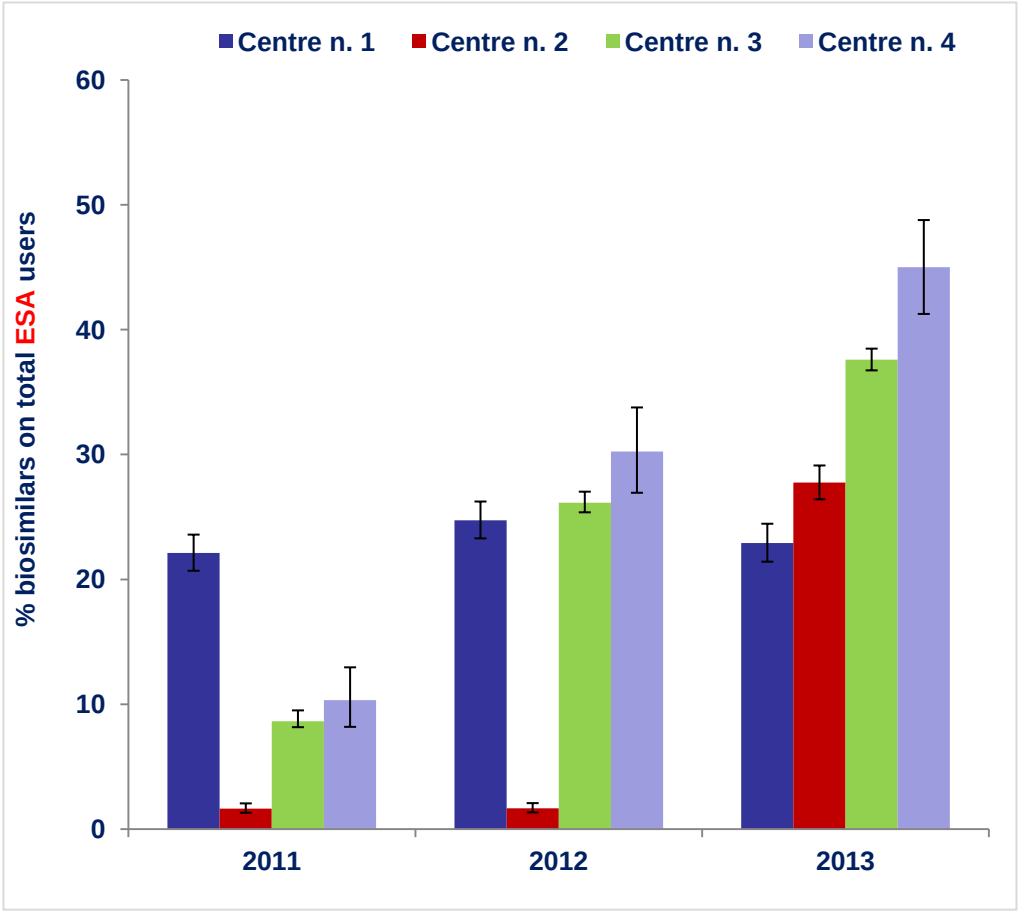
Uptake of biosimilar ESAs in different Italian Regions over time



% ESA biosimilars on total ESA users: ~40%

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Ingrasciotta Y *et al. How Much Are Biosimilars Used in Clinical Practice? A Retrospective Italian Population-Based Study of Erythropoiesis-Stimulating Agents in the Years 2009-2013. BioDrugs. 2015;29(4):275-84.*

Biosimilars vs originators: exp. and DDDs

Tabella 7.3.9. Biosimilari, erogazione attraverso le strutture pubbliche e prescrizione territoriale SSN nel 2015: confronto biosimilare versus il farmaco originator*

Gruppo	Sottogruppo	Spesa pro capite	Inc %	Δ % 15-14	DDD/1000 ab die	Inc %	Δ % 15-14
Epoetina	**Totale**	**2,01**	**100,0**	**-6,4**	**1,80**	**100,0**	**7,4**
	Originator[1]	1,23	61,4	-21,4	0,88	48,7	-17,1
	Biosimilari[2]	0,78	38,6	34,4	0,92	51,3	49,0
Fattori della crescita	**Totale**	**0,29**	**100,0**	**-16,5**	**0,03**	**100,0**	**7,5**
	Originator[3]	0,10	34,9	-33,8	<0,05	11,8	-32,0
	Biosimilari[4]	0,19	65,1	-3,0	0,03	88,2	16,5
Somatropina	**Totale**	**0,40**	**100,0**	**-26,8**	**0,07**	**100,0**	**7,1**
	Originator[5]	0,29	73,7	-34,4	0,05	62,5	-0,0
	Biosimilari[6]	0,10	26,3	8,8	0,03	37,5	21,5
Follitropina alfa	**Totale**	**0,76**	**100,0**	**-3,8**	**0,08**	**100,0**	**-0,9**
	Originator[7]	0,75	99,6	-4,1	0,08	99,6	-1,3
	Biosimilari[8]	0,00	0,4	-	<0,05	0,4	-
Infliximab	**Totale**	**1,55**	**100,0**	**-2,4**	**0,26**	**100,0**	**0,6**
	Originator[9]	1,42	91,6	-10,6	0,24	89,4	-10,1
	Biosimilari[10]	0,13	8,4	-	0,03	10,6	-

*il farmaco utilizzato come confronto nello studio clinico
[1] Eprex®; [2] Binocrit®, Retacrit®;
[3] Granulokine®, Neupogen®; [4] Nivestim®, Tevagrastim®, Zarzio®;
[5] Genotropin®; [6] Omnitrope®;
[7] Gonal-F®; [8] Bemfola®;
[9] Remicade®; [10] Inflectra®, Remsima®;

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Trends of expenditure and consumptions

Figura 7.3.10. Incidenza (%) dei farmaci biosimilari sulla spesa dei farmaci biosimilari e del farmaco originator: anno 2015

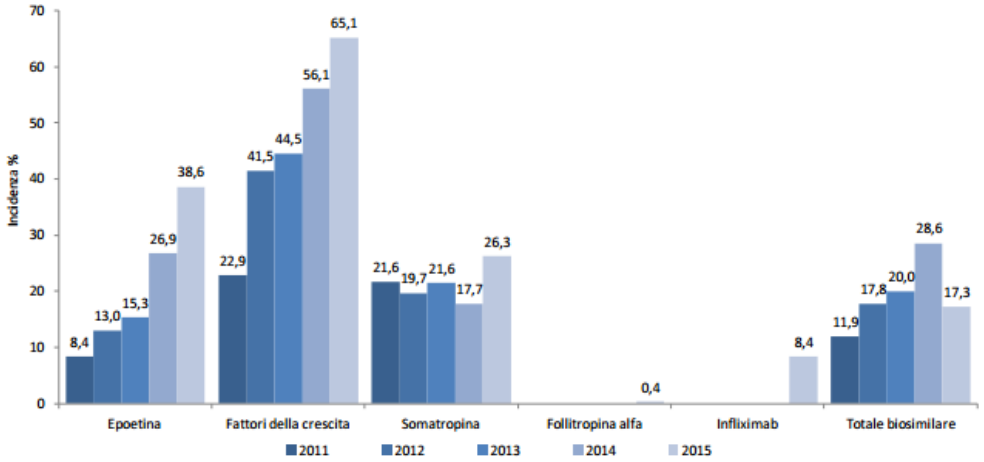
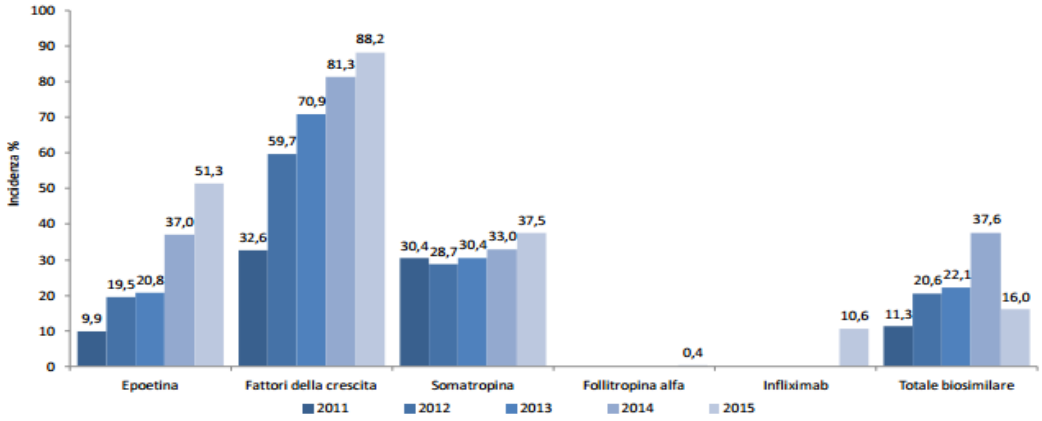


Figura 7.3.11. Incidenza (%) dei farmaci biosimilari sui consumi dei farmaci biosimilari e del farmaco originator: anno 2015



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Further updated information

Furthermore, the following update is provided on biosimilars most recently reimbursed and available to the Italian patients:

•Etanercept: a biosimilar of Enbrel was indeed reimbursed in 2016 with about 30% price reduction compared to its originator following the negotiation process.
•Infliximab: additional biosimilars of the originator Remicade are now available and reimbursed. Overall, approximately 25% price reduction has been negotiated for all infliximab biosimilars.

Of note, the negotiation process for the definition of price and reimbursement of the biosimilar of Mabthera (rituximab), recently approved by EMA, is currently ongoing at the Italian Medicines Agency.

Conclusions

- The uptake of generic medicines is still limited compared to other EU Member States
- Regional variability at the national level
- Increasing trends for the uptake of biosimilars
- Final Court decision on immediate reimbursability (with no negotiation) expected by end of year.

Thank you for your attention

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